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From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

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WRITTEN OPINION

(PCT Rule 66)

Date of mailing
(day/month/year)

03.09.97

Applicant's or agent's file reference DCW	REPLY DUE	within 3 months/days from the above date of mailing
International application No. PCT/ GB 96/ 02802	International filing date (day/month/year) 14/11/1996	Priority date (day/month/year) 14/11/1995
International Patent Classification (IPC) or both national classification and IPC A61M27/00		
Applicant KCI MEDICAL LIMITED et al.		

1. This written opinion is the first (first, etc.) drawn up by this International Preliminary Examining Authority.
2. This report contains indications and corresponding pages relating to the following items:

- I Basis of the opinion
- II Priority
- III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV Lack of unity of invention
- V Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI Certain documents cited
- VII Certain defects in the international application
- VIII Certain observations on the international application

3. The applicant is hereby invited to reply to this opinion.

When? See the time limit indicated above. The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.2(d).

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3.
For the form and the language of the amendments, see Rules 66.8 and 66.9.

Also For an additional opportunity to submit amendments, see Rule 66.4.
For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4bis.
For an informal communication with the examiner, see Rule 66.6.

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.

4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 14/03/1998

Name and mailing address of the IPEA/ European Patent Office D-80298 Munich Tel. (+ 49-89) 2399-0, Tx: 523656 epmu d Fax: (+ 49-89) 2399-4465	Authorized officer Examiner <u>A. Germano</u>
	Formalities officer (incl. extension of time limits) Telephone No. <u>Uwe</u> <u>Martine Edel</u>

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I. Basis of the opinion

1. This opinion has been drawn up on the basis of (Substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed".):

the international application as originally filed.

the description, pages _____, as originally filed,
pages _____, filed with the demand,
pages _____, filed with the letter of _____,

the claims, Nos. _____, as originally filed,
Nos. _____, as amended under Article 19,
Nos. _____, filed with the demand,
Nos. _____, filed with the letter of _____,

the drawings, sheets/fig. _____, as originally filed,
sheets/fig. _____, filed with the demand,
sheets/fig. _____, filed with the letter of _____,

2. The amendments have resulted in the cancellation of:

the description, pages _____.
 the claims, Nos. _____.
 the drawings, sheets/fig. _____.

3. This opinion has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

4. Additional observations, if necessary:

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IV. Lack of unity of invention

1. In response to the invitation (Form PCT/IPEA/405) to restrict or pay additional fees the applicant has:

- restricted the claims.
- paid additional fees.
- paid additional fees under protest.
- neither restricted nor paid additional fees.

2. This Authority found that the requirement of unity of invention is not complied with for the following reasons and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees:

1. The application as claimed comprises 3 different inventions, namely:

- a portable therapeutic apparatus according to claims 1 and 2,
- a therapeutic apparatus according to claims 3 and 4, and
- a therapeutic apparatus according to claims 5 to 7.

2. In order that an international application may contain more than one invention, the inventions must be so linked, as to form a single general inventive concept.

This concept finds expression in the claims in terms of the same or corresponding special technical features, where the expression "special technical features" means the features which define the inventive contribution that the claimed invention makes over the prior art.

2.1 In the present case the common matter of independent claims 1, 3 and 5 is: "a therapeutic apparatus for stimulating the healing of a wound in mammals comprising a suction pump and a canister for containing (or col-

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lecting) liquids drawn from the wound, the canister including means for connection to the region of the wound".

This matter is not new, see section V-2, and thus not inventive, and therefore it does not comprise any special technical feature which may form the inventive concept linking the invention according to the independent claims.

In consequence the requirements of Rule 13.1 PCT are not met.

3. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this opinion:

all parts.

the parts relating to claims Nos. _____.

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V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement

1. STATEMENT

Inventive Step (IS) Claims 1-7 _____
Claims _____

Industrial Applicability (IA) Claims _____
 Claims _____

2. CITATIONS AND EXPLANATIONS

1. The closest prior art document as regards the subject-matter of claim 1 appears to be US-A-4 710 165. This document discloses, see col. 4, lines 20-25 and col. 5, lines 1-54 and the drawings, a portable therapeutic apparatus for stimulating the healing of a superficial wound in a person, which comprises a housing (16) containing a suction pump (10) and a canister (20) for containing fluids drawn from the wound by said pump (10), said canister (20) including means for connection in the region of the wound and a harness (18) or belt for supporting the housing (16) on the person.

The apparatus described in claim 1 merely differs from this disclosure in that the claim specifies that the means for connection included in the canister are for connection to a dressing.

This feature is not explicitly disclosed in the above mentioned prior art. Insofar as this feature may be considered to involve a difference between the prior art

and claim 1, see section VIII, it appears that the feature is described for the same purpose at least in WO-A-96/05873, see drawings and abstract.

Therefore the subject-matter of claim 1 does not involve an inventive step and the claim does not meet the requirements of Art. 33(3) PCT.

2. The feature of claim 1 is obvious and further is disclosed for the same purpose in WO-A-80/02182. Therefore the claim does not involve an inventive step and does not meet the requirements of Art. 33(3) PCT.
3. The closest prior art document as regards the subject-matter of claim 3 appears to be WO-A-94/20041. This document discloses, see page 12, line 8 to page 18, line 35 and figs. 1, 8-11, a therapeutic apparatus for stimulating the healing of a wound in mammals which comprises a porous pad (10), which is permeable to liquids for introduction into the wound, a dressing (18) for covering the wound and providing a substantially air-tight seal around the wound, a drainage tube (12, 36) connecting the pad (10) to a suction pump (40) so that the suction can be applied to the wound to draw fluids therefrom, said tube (12, 36) being connected to the pump (40) via a canister (28,33) for collecting liquids sucked from the wound and a filter barrier (38a) located between the canister (28,33) and the suction pump (40).

The subject-matter of claim 3 differs from this disclosure in that:

- a) the filter barrier is located in the canister at the outlet side, and
- b) pressure detecting means are arranged to detect the

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pressure changes in the drainage tube between the canister and the pump to signal a pressure change when the liquid in the canister covers a substantial part of the filter barrier, thus indicating a full canister.

However, feature a) is disclosed for the same purpose in the document GB-A-2 220 357, see page 8, lines 2-16 and fig. 1, and feature b) is disclosed for the same purpose in DE-U-295 04 378, see the whole document.

Therefore the subject-matter of claim 3 does not involve an inventive step and the claim does not meet the requirements of Art. 33(3) PCT.

4. The feature of claim 4 is disclosed for the same purpose in all the three documents cited at point 3. above and does not involve an inventive step.

Therefore claim 4 does not meet the requirements of Art. 33(3) PCT.

5. The closest prior art document as regards the subject-matter of claim 5 appears to be WO-A-94/20041. This document discloses, see page 12, line 8 to page 18, line 35 and figs. 1, 8-11, a therapeutic apparatus for stimulating the healing of a wound in mammals which comprises a porous pad (10), which is permeable to liquids for introduction into the wound, a dressing (18) for covering the wound and providing a substantially air-tight seal around the wound, a drainage tube (12, 36) connecting the pad (10) to a suction pump (40) so that the suction can be applied to the wound to draw fluids therefrom, said tube (12, 36) being connected to the pump (40) via a canister (28,33) for collecting liquids sucked from the wound and a filter barrier (38a) located between the canister (28,33) and the suction pump (40).

The subject-matter of claim 5 differs from this disclosure in that it comprises an additional conduit connecting the porous pad to pressure detecting means, whereby the pressure substantially at the wound site may be monitored.

However this feature is suggested for the same purpose in DE-A-4 306 478, see fig. 4 and relevant part of the description.

Therefore the subject-matter of claim 5 does not involve an inventive step and the claim does not meet the requirements of Art. 33(3) PCT.

6. The features of dependent claims 6 and 7 are also disclosed for the same purpose in DE-A-4 306 478 and therefore do not involve an inventive step.

In consequence also claims 6 and 7 do not meet the requirements of Art. 33(3) PCT.

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

1. Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the documents US-A-4 710 165 and WO-A-94/20041 is not mentioned in the description, nor are these documents identified therein.
2. The description is not in conformity with the claims as required by Rule 5.1(a)(iii) PCT.
3. The independent claims 1, 3 and 5 are not in the two-part form in accordance with Rule 6.3(b) PCT, which in the present case would be appropriate, with those features known in combination from the relevant prior art documents being placed in a preamble (Rule 6.3(b)(i) PCT) and with the remaining features being included in a characterising part (Rule 6.3(b)(ii) PCT).

The features which are known in combination from the relevant prior art documents and belong in the preamble the claims and the relevant prior art documents are indicated in section V-2.

In this section are also indicated the features which, according to the present wording of the independent claims, should be included in the characterizing portion.

If, however, the applicant is of the opinion that the two-part form would be inappropriate, then reasons therefor should be provided in the letter of reply. In addition, the applicant should ensure that it is clear from the description which features of the subject-matter of the independent claims are known from the closest prior art documents (see the PCT Guidelines

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PCT/GL/3 III, 2.3a).

4. The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).

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VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

From the wording of claim 1 it is not clear whether or not the dressing mentioned at the last but one line of the claim (...for connection to a dressing in the region...) forms part of the claimed apparatus.

This uncertainty leads to a lack of clarity within the meaning of Art. 6 PCT. In section V-2 it has been supposed that the apparatus comprises the dressing and in consequence the subject-matter of claim 1 was considered deprived from an inventive step. If the apparatus would not comprise this feature, then the matter of claim 1 would appear to be completely anticipated by the prior art cited at point 1. of said section.